PATENT

IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

Applicant: Stevens, Fred J. et al.

Application: "DEVICE FOR DETECTING MOLECULES, METHOD FOR DETECTING MOLECULES"

Serial No.: 09/368,989

Filed: August 5, 1999

Art Unit: 1641

Examiner: Dr. Lisa V. Cook

CERTIFICATE OF MAILING: I hereby certify that this correspondence is being deposited with the United States Postal Service pursuant to 37 C.F.R. 1.8 as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on October 23, 2001 (Date of Deposit)

Michael J. Cherskov
Name of Representative

Signature of Representative

10/23/01
Date of Sig.

Assistant Commissioner for Patents
Washington, D.C. 20231

20 North Wacker Drive
Chicago, IL 60606
312-621-1330

37 CFR 1.131 Affidavit
of Fred J. STEVENS

Dear Sir:

Dr. Fred J. Stevens, being first duly sworn, deposes and says that:

1. I am a joint inventor of the invention described and claimed in the above-identified patent application.

2. I declare that conception of the invention occurred in the United States.

3. A device for detecting molecules and the method for detecting molecules as described and claimed in the instant application was reduced to practice at least as

early as April 27, 1998. An invention report (copy attached hereto as Exhibit A) describing an embodiment of the invention was prepared by Victoria Henson-Apollonio on April 27, 1998, and signed by myself and a co-inventor on May 11, 1998.

4. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and may jeopardize the validity of the aforesaid patent application.

Date: 10-19-2001

Fred J. Stevens

INVENTION REPORT

ANL CASE #: ANL-IN-98-026

DOE CASE #:

INVENTORS: Fred J. Stevens
Marianne Schiffer

TITLE: JANUSBODY: A COMPACT MOLECULES WITH ANTIBODY-ANTIGEN BINDING CHARACTERISTICS

DESCRIPTION: This invention embodies the manufacture of a new type of synthetic protein, a "Janusbody". Such a molecule would possess less complexity, but would retain the binding characteristics of a conventional antibody molecule. A "Janusbody" is a compact, bivalent protein consisting of a dimeric assembly of a single antibody domain.

Conventional antibody molecules are used in a wide variety of applications from detection/diagnostic systems and assays to treatment protocols. Currently, antibodies are manufactured in the form of polyclonal antisera by immunizing animals and subsequent collection of sera, as monoclonal antibodies produced by tissue cell culture, or as recombinant antibody molecules produced by bacteria. Janusbody molecules would be produced by bacteria; however, this protein would represent only a portion of a VL domain, consisting of complementarity determining segments (CDRs) and framework (FR turns) regions. This invention would simplify the bacterial production, both with regard to manufacture of any one protein and the method by which changes could be introduced to shift production to another Janusbody molecule with slight differences in amino acid sequence.

The inventors have demonstrated that dimers of one VL domain fragment form a bivalent molecule (two binding sites at either end) in which each site retains the binding characteristics of a conventional antibody molecule. Additional constructs of such proteins that represent this VL domain with introduced amino acid substitutions at one or two sites in the domain have also yielded molecules that retain specific binding characteristics. Additional experiments using additional constructs would be desirable in order to prove the general applicability of this invention.

This invention also covers methods that could be used to manufacture collections or "libraries" of Janusbody genes that differ slightly in their sequence. Each individual gene would lead to the production of a product with slighly different binding characteristics and specificity. This portion of the invention is a concept at this time.

BACKGROUND, INCLUDING RELATED ART: See attached report written by Fred Stevens.

PUBLICATIONS, REPORTS AND TALKS: None at this time.

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35 USC 205 AND 37 CFR 401

INVENTORS' STATUS: The inventors, Fred Stevens, and Marianne Schiffer, are employed by Argonne National Laboratory in the Center for Mechanistic and Biotechnology Division and are citizens of the United States. This invention was conceived under Contract N . W-31-109-ENG-38 between the U.S. Department of Energy (DOE) and The University of Chicago representing Argonne National Laboratory.

BADGE NUMBERS:

27475	09086
Fred J. Stevens	Marianne Schiffer

FUNDING SOURCE for research under which invention was conceived:

ANL: ____ LDRD (Laboratory Director Research & Development, previously called Exploratory Research Funds [ERF] or Program Development Funds [PDF])

Were LDRD (or ERF/PDF) funds used to support research that preceded the research during which the invention was conceived? __X__ No ____ Yes

DOE: FWP No. 61000/B00106 B&R Code: KP-11-01

Non-ANL/DOE Sponsor: Name of organization: _____

Type of organization: ____ Federal ____ State ____ Private ____ Not-for-profit

Type of funding document or agreement: ____ WFO ____ CRADA ____ HTSCA ____ MIPR

Other (specify): _____ Agreement No.: _____

PROBABLE VALUE: This invention covers the manufacture of a type of protein molecule that could replace conventional antibodies currently used in a wide variety of applications.

RECOMMENDATIONS: The recommendations of ITD personnel will be provided later.

EXCEPTIONAL CIRCUMSTANCES: This invention is not an exceptional circumstance invention.

REPORT DATED: April 27, 1998 - Victoria Henson-Apollonio

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READ AND UNDERSTOOD BY:

[signature]	5/11/98	Derrick K. Hanson	5/11/98
Inventor Signature	***Date***	***Witness Signature***	***Date***
Gloriana Schaffer	5/11/98	Priscilla Williams Stevens	5/11/98
Inventor Signature	***Date***	***Witness Signature***	***Date***